

**Amendments to the Drawings:**

The attached sheet 3/8 of drawings includes changes to Figs. 3A and 3B. This sheet 3/8, which includes Figs. 3A and 3B, replaces the original sheet 3/8.

Attachment: Replacement Sheet 3/6

### **REMARKS/ARGUMENTS**

Claims 1-29 and 31-48 are pending in this application. Claim 30 has been previously cancelled. Reconsideration of this Application and entry of this Amendment is respectfully requested.

Applicants have amended claims 1 and 3 and canceled claims 2 and 43-45. Support for the amendments to claim 1 can be found in Figures 3A and 3B and in the specification in paragraphs 0005 and 0015. Claim 3 has been amended solely to correct dependency. No new matter has been introduced as a result of the claim amendments.

By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

#### **Specification**

Paragraph 0021 of the specification has been amended to add reference numbers to features of stents 30a and 30b depicted in Figures 3A and 3B as originally filed. No new matter has been added as a result of the amendment to the specification.

#### **Drawings**

Figures 3A and 3B have been amended to add reference numbers to features of stents 30a and 30b as originally filed. No new matter has been added as a result of the amendments to Figures 3A and 3B.

#### **35 U.S.C. §101 Rejections**

Claims 1-29 and 31-48 have been rejected under 35 USC §101 allegedly because the disclosed invention is inoperative and therefore lacks utility. The Examiner has stated that the invention is inoperable because one possible material from which the medical device can be manufactured, nitinol, does not compress after implantation. Applicants respectfully traverse.

Applicants have amended claim 1 to indicate that the contractibility of the claimed stent is a function of the stent's shape rather than the material from which the stent is formed. Since the contractibility of the stent is not a function of the stent's material, the possibility of forming the stent from nitinol does not render the invention in operable.

In light of the arguments presented *supra*, Applicants respectfully request the Examiner withdraw the rejections on this basis.

### **35 U.S.C. §112 Rejections**

Claims 1-29 and 31-48 have been rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse.

As discussed *supra*, Applicants have amended claim 1 to indicate that the contractibility of the claimed stent is a function of the stent's shape rather than the material from which the stent is formed. Therefore, the specification is enabled for a helical stent as depicted, *intra alia*, in Figure 3.

In light of the arguments presented *supra*, Applicants respectfully request the Examiner withdraw the rejections on this basis.

### **35 U.S.C. §102 Rejections**

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.*

Claims 1-3, 6, 7, 17-19, 40-42 have been rejected under 35 USC §102(e) as being anticipated by Jansen et al. (US 6,579,308). Applicants respectfully traverse.

Jansen does not disclose a stent having a helical configuration wherein each turn of the helix has a diameter independent of the diameter of any other turn. Nor does Jansen disclose a stent capable of a shape-accommodating contraction.

Because Jansen et al. fails to disclose each and every element as set forth in amended claim 1, from which claims 2-3, 6, 7, 17-19 and 40-42 depend, the pending claims are not anticipated under 35 USC §102(b). The Examiner is respectfully requested to withdraw the rejection on that basis.

Claims 43-45 have been rejected under 35 USC §102(b) as being anticipated by Ragheb et al. (US 6,096,070). Claims 43-45 have been canceled, therefore Applicants respectfully assert that the rejection under 35 USC §102(e) over Ragheb et al. is moot and request the withdrawal of this rejection.

### **35 U.S.C. §103 Rejections**

To reject a claim under 35 U.S.C. §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. *In re Bell*, 26 USPQ.2d 1529 (Fed. Cir. 1992). The Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims. See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. *In re Oetiker*, 24 USPQ.2d 1443 (Fed Cir. 1992).

Claims 4 and 5 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Maas (US 4,553,545) or Segal (US 5,755,708) or Summers et al. (US 5,772,668) or Melzer et al. (US 6,280,385). Applicants respectfully traverse.

As discussed *supra*, Jansen does not teach or suggest a stent having a helical configuration wherein each turn of the helix has a diameter independent of the diameter of any other turn. Nor does Jansen disclose a stent capable of a shape-accommodating contraction. Furthermore, Jansen does not teach or suggest a helical stent wherein the diameter of the middle portion is greater than the diameter of either end portion. Thus, Jansen does not teach or suggest the contractible stent of the instant claims.

Maass, Segal, Summers and Melzer, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 4 and 5, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn and wherein the diameter of the middle portion is greater than the diameter of either end portion.

Claims 8, 9, 11, 12, and 43-45 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Ragheb '070. Applicants respectfully traverse. Claims 43-45 have been canceled.

Ragheb does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 8, 9, 11 and 12, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claim 10 has been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Ragheb '070 as applied to claim 8, and further in view of Wright et al. (US 6,273,913). Applicants respectfully traverse.

Ragheb and Wright, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claim 10, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claims 13-16 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Eisert (US 2005/0192664) and Hunter et al. (US 6,333,347, hereinafter "Hunter '347"). Applicants respectfully traverse.

Eisert and Hunter '347, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 13-16, namely a contractible helical stent which contracts when the

aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claims 20-27 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Narciso, Jr. (US 5,419,760). Applicants respectfully traverse.

Narciso, Jr. does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 20-27, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claims 28, 29, 31-39, and 48 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Hunter et al. (US 5,716,981, hereinafter "Hunter '981"). Applicants respectfully traverse.

Hunter '981 does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 28, 29, 31-39 and 48, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claims 31-36 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Ragheb '070 further in view of Vallana et al. (US 2003/0028242) and Hunter '981. Applicants respectfully traverse.

Ragheb, Vallana and Hunter '981, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 31-36, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claim 46 has been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Clouse (US 5,211,658). Applicants respectfully traverse.

Clouse does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claim 46, namely a contractible helical stent

which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

Claim 47 has been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Clouse (US 5,211,656) as applied to claim 46, and further in view of Falotico et al. (US 2003/0060877). Applicants respectfully traverse.

Clouse and Falotico, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claim 47, namely a contractible helical stent which contracts when the aneurysmal site contracts due to healing, wherein each turn of the helix has a diameter independent of the diameter of any other turn.

### **Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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